

HAEMONETICS"

HAEMONETICS CORPORATION
400 Wood Road
Braintree, Massachusetts 02184-9144
Telephone (781) 848-7100

6551 '99 DEC -3 A9:23

December 2, 1999

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: **Docket No. 98N-0673**, Revisions to the Requirements Applicable to Blood,
Blood Components, and Source Plasma

Dear Sir/Madam:

The purpose of this letter is to provide comments on the direct final rule referenced above, specifically pertaining to Section 640.62 Medical Supervision. In reviewing the amended rule, we applaud the fact that the agency appears to have relaxed the requirement for the physical presence of a physician for plasmapheresis [¶ 640.22(b) and ¶ 640.32(b)] and the collection of source plasma [¶ 640.62]. However, **as** amended, it is the position of Haemonetics Corporation that the proposed rule is potentially confusing and may be difficult to comply with, within individual blood collection centers and mobile activities. Specifically, the following comments are made:

1. The proposed section requires that "a qualified licensed physician shall be available to attend to the donor within 15 minutes.. ." without providing any rationale for the specification of this time constraint. Nor does the proposed rule define whether "available to attend" indicates that the physician must be able to be physically present within 15 minutes or whether telephonic advice and consultation is authorized.
2. The availability of the physician within the stated timeframe does not differentiate between seemingly routine activities (such as the determination of donor suitability) and the potentially more critical management of donor adverse reactions that may occur during whole blood or apheresis collection procedures. Nor does the proposed rule acknowledge the potential availability of other medically qualified personnel (non-physician) within blood centers or of the availability of emergency medical services through the 911 call system, should an adverse event occur.

3. The proposed direct final rule appears to ignore the operational necessity within the United States to collect blood products via mobile collection centers. Under the proposed 15 minute time constraint specified in Section 640.62, it would be unrealistic, if not impossible, at mobile sites to expect physician attendance on a routine basis and reliance on the 911 emergency services would likely be more appropriate and logical in response to the medical need of the donor.
4. Finally, consideration should be given to the expected risks historically associated with the donation of blood, blood components, and source plasma. Direct medical supervision should be aligned with the anticipated risks associated with the applicable procedure or activity under consideration. Clearly, the agency's view on the administration of immunized red cells is that the risk necessitates the availability of the physician on the premises during the procedure, since this has been specified in the proposed rule. Regarding apheresis collection of blood components however, where upwards of 13 million procedures are performed annually in the US, adverse events are rare enough that relying on nearby emergency medical facilities is sufficient to ensure that no adverse reactions go untreated.

Once again, we recognize the agency's attempt to modify the requirement for the physical presence of a physician during collection activities, as currently mandated in Section 640.62. However, it is not clear that the proposed direct final rule will add value, increase donor safety or beneficially affect public policy in the management of blood, blood component, and source plasma collection activities. Potential donor safety concerns would appear to be better managed through a requirement for documented standard operating procedures within the donor center (whether a fixed facility or mobile activity), as outlined in Section 640.4(a) for the collection of Whole Blood.

Respectfully submitted,



Peter A. Tomasulo, MD, FACP
President Surgical Business
Corporate Medical Director



Federal Expre

SILVIO MACIEL
Haemonetics Corporation
400 Wood Road
Braintree
(617)848-7100

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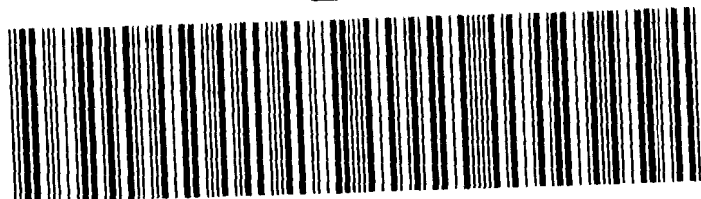
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HAEMONETICS CORPORATION
400 Wood Road, Braintree, Massachusetts 02184-9114

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5630 Fishers Lane, Room 1061
Rockville, MD 20852

dept. 50.520 x9785

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